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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/773,100

02/05/2004

Ulrich Pessara

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05/22/2006

FISH & NEAVE IP GROUP  
ROPES & GRAY LLP  
ONE INTERNATIONAL PLACE  
BOSTON, MA 02110-2624

EXAMINER

WHALEY, PABLO S

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/773,100	<b>Applicant(s)</b> PESSARA ET AL.	
	<b>Examiner</b> Pablo Whaley	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 29-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☒ Claim(s) 4-28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *APPLICANT'S ELECTION*

Applicant's election with traverse of Group I (Claims 1-28) in the reply filed on 3/7/06 is acknowledged. The traversal is on the ground(s) that Groups I-IV share common features which would facilitate searching. This is not found persuasive because the examination process requires a search of non-patent literature, U.S. patent publications, U.S. patents, as well as foreign patent literature. The requirement is still deemed proper and is therefore made FINAL. Claims 29-32 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim.

Applicant's election with traverse of Specie A (cDNA molecules), Specie B (screening for the function of a secreted protein), and Specie C (calcium phosphate transfection) in the reply filed on 3/7/06 is acknowledged. The traversal regarding a lack of search burden for the above species is persuasive, therefore the specie election for Species A, B, and C is withdrawn and all species are rejoined.

### *OBJECTIONS*

Claims 4-28 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from a multiple dependent claim (instant claim 3). See MPEP § 608.01(n). Accordingly, the claims 4-28 have not been further treated on the merits.

### *CLAIMS UNDER EXAMINATION*

Claims herein under examination are Claims 1-3.

**CLAIM REJECTIONS - 35 USC § 112, 2<sup>nd</sup> Paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "optionally automated separation of endotoxins...". As written, it is unclear whether "optionally" is referring to the actual method step being optional or to the automated separation being optional. Clarification is requested.

Claim 1 recites the limitation "automated transfection of cells with the DNA obtained in step (c) or, if the cells are bacteria, obtained in step (d) by means of a third robot." It is unclear how the material which has been "obtained in step (d)" is related to the step of "automated transfection." Clarification is requested. Claims 2-3 are rejected as they depend either directly or indirectly from instant claim 1.

### **CLAIM REJECTIONS - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 are rejected under 35 U.S.C. 102 (a) and (e) as being anticipated by Vogels et al. (US Pat. #6,340,595; Filed Jul. 21, 1999).

Vogels et al. teach means and methods of high-throughput screening of gene function using adenoviral libraries for functional genomics applications. More specifically, Vogels et al. teach the following aspects of the instant invention:

- Automated colony-picking robot; plasmid DNA isolation, lysis, and pelleting (i.e. separation) [Col. 64, lines 25-55], as in instant claim 1 (steps a, b, c)
- Methods suited for endotoxin separation in high-throughput DNA isolation (i.e. automated methods) [Col. 52, lines 5-30], as in instant claim 1 (step d).
- Transfection of cells with isolated DNA [Col. 64, lines 58-67], as in instant claim 1 (step e).

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- High-throughput construction of a gene expression library for use in automated screening [Col. 65, lines 10-35], as in instant claims 1 (step f) and 2.
- Sample nucleic acids comprising DNA, cDNA, oligonucleotides, and encoded polypeptides [Abstract], as in instant claim 3.
- Screening for altered phenotype, which is used as the basis to assign function to the product encoded by the sample nucleic acids [Col. 3, lines 30-60], as in instant claim 1.
- Transfection using calcium phosphate [col. 42, lines 45-55], as in instant claim 1.

Claims 1-3 are rejected under 35 U.S.C. 102 (e) as being anticipated by Stemmer et al. (US Pat. No. 6,500,617; Filed: Apr. 22, 1999).

Stemmer et al. teach automated methods of producing libraries of recombinant pest resistant genes and screening for properties of interest [Abstract]. More specifically, Stemmer et al. teach the following aspects of the instant invention:

- All steps including cell picking, cell growth, sample preparation, and analysis are automated and carried out at various robotic workstations [Col. 53, lines 35-50], as in instant claim 1.
- automated colony picking robot (Q-bot) that acquires a nucleic material from cells; lysis of cells and centrifugation (i.e. separation of DNA from cellular debris) [Col. 55, lines 1-20], and cotransfection of cells with cells with viral DNA [col. 52, lines 1-7]
- cells containing recombinant DNA are screened to detect desired property [Col. 44, lines 15-25]; as in instant claim 1.
- DNA isolation from pools (i.e. libraries) or clones [Col. 15, lines 65 through Col. 16, lines 1-5] and genomic DNA [Col. 57, lines 25-32], as in instant claims 2 and 3.

#### **PRIOR ART MADE OF RECORD**

The prior art made of record and not relied upon which is considered pertinent to applicant's disclosure:

- Regelin et al. (J. Biomolecular Screening, 2001, Vol. 6, No. 4, p.245-254)
- Grimm et al. (Biotechniques, March 2002, Vol. 32, No. 3, p.670-677).

#### **CONCLUSION**

Claims 4-28 are objected to and Claims 1-3 are rejected for reasons set forth above. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

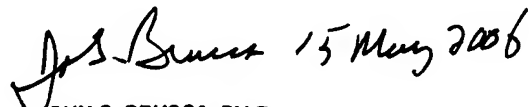
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pablo S. Whaley

Patent Examiner  
Art Unit 1631  
Office: 571-272-4425

 15 May 2006  
JOHN S. BRUSCA, PH.D.  
PRIMARY EXAMINER